IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

R.J. REYNOLDS TOBACCO COMPANY, *et al.*,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*,

Defendants.

Civil Action No. 6:20-cv-00176

DEFENDANTS' COMBINED MOTION FOR SUMMARY JUDGMENT AND OPPOSITION TO PLAINTIFFS' MOTION FOR POSTPONEMENT

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INTRODUCTION

"[T]hat people already know smoking is dangerous does not mean that they know all the health consequences of smoking." *R.J. Reynolds Tobacco Co. v. FDA*, 96 F.4th 863, 885 n.71 (5th Cir. 2024), *cert. denied*, No. 24-189, 2024 WL 4874678 (U.S. Nov. 25, 2024). In large part, that is why Congress directed the Food and Drug Administration (FDA) to "issue regulations that require color graphics depicting the negative health consequences of smoking," to "promote greater public understanding of the risks associated" with smoking. Pub. L. No. 111-31 § 201(d) (codified at 15 U.S.C. § 1333(d)).

To carry out that statutory mandate, FDA spent years developing new cigarette health warnings that will help narrow this deficit in public knowledge by describing and depicting some of the many serious, but lesser-known, health consequences of smoking. *See Tobacco Products; Required Warnings for Cigarette Packages and Advertisements*, 85 Fed. Reg. 15,638 (Mar. 18, 2020) (to be codified at 21 C.F.R. pt. 1141) ("the Rule" or "the Final Rule"). "[T]he agency tested the Warnings' effectiveness in raising consumer awareness and then refined them based on those results," *R.J. Reynolds*, 96 F.4th at 884—including by carrying out some of the largest quantitative consumer-research studies ever conducted on cigarette warnings. In doing so, as the Fifth Circuit observed, "FDA and Congress have well justified the extent of the new warnings." *Id.*

For years, Plaintiffs insisted that "the government's approach would render the First Amendment a dead letter." Pls.' Opp'n & Reply at 2, ECF No. 59. But the Fifth Circuit has now squarely rejected Plaintiffs' First Amendment claim—that is, Plaintiffs' primary merits argument—holding that "[t]he Warnings are both factual and uncontroversial, despite the emotional impact the graphics may have." *R.J. Reynolds*, 96 F.4th at 875. In short, "because the Warnings address a legitimate state interest, are justified, and are not unduly burdensome in light of that interest and justification, the Warnings survive" constitutional scrutiny. *Id.* at 887. The Fifth Circuit then denied Plaintiffs' petition for rehearing en banc without calling for a response from the government and without any noted dissent, after "no member of the panel or judge in regular active service requested that the court be polled on rehearing en banc." *R.J. Reynolds*, No. 23-40076, ECF No. 162-1 (5th Cir.

May 21, 2024). The Supreme Court likewise denied Plaintiffs' petition for a writ of certiorari without any noted dissent. *R.J. Reynolds*, No. 24-189, 2024 WL 4874678 (U.S. Nov. 25, 2024).

The Rule is now in effect. So, in a last-ditch effort to further delay their compliance obligations as long as possible, Plaintiffs now (again) move to "postpone" the effective date of the Rule—despite the government having already agreed not to enforce it against Plaintiffs until late-February 2026, and even though it was Plaintiffs that sought (and obtained) a lengthy abeyance of all further district-court proceedings in this case earlier this year, over Defendants' objection. *See* ECF Nos. 114-16.

Plaintiffs' motion should be denied and, instead, the Court should enter summary judgment for Defendants. For the most part, Plaintiffs try to repackage their failed First Amendment arguments into reasons why the Rule is arbitrary-and-capricious under the Administrative Procedure Act (APA). But the Fifth Circuit's unanimous rejection of Plaintiffs' First Amendment arguments is effectively fatal to Plaintiffs' refurbished versions of those very same arguments under the APA. And regardless, the Fifth Circuit was correct to say that FDA "well justified" the Rule. *R.J. Reynolds*, 96 F.4th at 884.

Plaintiffs' remaining arguments are more cursory, but equally meritless. For example, Plaintiffs claim they were entitled to all of FDA's raw study data during the comment period and complain of insufficient opportunity to comment on FDA's qualitative study reports—all of which they have now had possession of for roughly half-a-decade. But under Fifth Circuit precedent that Plaintiffs (still) ignore, FDA had no obligation to solicit comments on raw data, as it disclosed more than sufficient information to facilitate meaningful feedback on the agency's studies through the release of lengthy and detailed reports on those studies. And FDA in fact provided a standalone comment period dedicated solely to its qualitative study reports. The APA requires no more—even accepting the (dubious) proposition that any of these choices were in any way prejudicial.

FDA also complied with the Tobacco Control Act (TCA) when it modified the default text of the warnings after finding that "such a change would promote greater public understanding of the risks associated with the use of tobacco products." 15 U.S.C. § 1333(d)[2]. Congress explicitly authorized FDA to do so, in a provision appropriately titled "Change in Required Statements." Plaintiffs' counterintuitive interpretations of that provision, by contrast, are entirely atextual.

In sum, implementing an explicit mandate from Congress, FDA developed "factual and uncontroversial" warnings that will improve the public's understanding of the negative health consequences of smoking, *R.J. Reynolds*, 96 F.4th at 875; it "well justified" those warnings with a robust rulemaking record built over many years, *id.* at 884; and it complied with every applicable substantive and procedural requirement along the way. It is long past time for this litigation to end, and for Plaintiffs to finally take their first steps—over the next fourteen months—to implement Congress's will: that the warnings on their deadly products be updated for the first time in more than a generation.

STATEMENT OF THE ISSUES

The dispositive issues presented by Defendants' motion for summary judgment are whether the Rule violates the Administrative Procedure Act or the Tobacco Control Act.

BACKGROUND

Congress enacted the TCA based on decades of evidence about the health risks of tobacco products and the industry's deceptive marketing practices. Tobacco use "is the foremost preventable cause of premature death in America" and "causes over 400,000 deaths in the United States each year," with approximately 8.6 million Americans suffering chronic illnesses related to smoking. Pub. L. No. 111-31, § 2(13), 123 Stat. 1776, 1777 (2009). "[T]obacco use, particularly among children and adolescents, poses the single most significant threat to public health in the United States." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161 (2000). That public-health harm is "inextricably linked" to nicotine addiction. 75 Fed. Reg. 69,524, 69,528 (Nov. 12, 2010). The tobacco industry has long depended on recruiting underage users who become addicted before age 18, and the "[a]dvertising, marketing, and promotion of tobacco products have been especially directed to attract young persons to use tobacco products." Pub. L. No. 111-31, § 2(15), 123 Stat. at 1777.

For decades, the tobacco industry intentionally misled its own customers and the public about the health risks and addictiveness of its products. *See United States v. Philip Morris USA, Inc.*, 566 F.3d 1095, 1121 (D.C. Cir. 2009) (per curiam). This industry has thus been built upon the twin pillars of a powerfully addictive product and deception about its harms, which has let cigarette use become deeply

entrenched in American society. As the Surgeon General put it, "[t]he tobacco epidemic was initiated and has been sustained by the aggressive strategies of the tobacco industry, which has deliberately misled the public on the risks of smoking cigarettes." 85 Fed. Reg. at 15,645.

I. STATUTORY BACKGROUND

In 1965, Congress enacted the Federal Cigarette Labeling and Advertising Act ("the Labeling Act"), Pub. L. No. 89-92, 79 Stat. 282 (1965), to establish a system of warnings on cigarette packages and advertisements through which "the public may be adequately informed about adverse health effects of cigarette smoking." 15 U.S.C. § 1331. Originally, the Labeling Act "required that a printed text-only warning appear on cigarette packages." 85 Fed. Reg. 15,640. That warning was later amended in the Public Health Cigarette Smoking Act of 1969. Pub. L. No. 91-222, 84 Stat. 87 (1970).

In the Comprehensive Smoking Education Act of 1984, Pub. L. No. 98-474, 98 Stat. 2200 (1984), Congress expanded the warning requirement to apply to both labeling and advertising. 85 Fed. Reg. 15,640. Congress' stated purpose was "to provide a new strategy for making Americans more aware of any adverse health effects of smoking, to assure the timely and widespread dissemination of research findings and to enable individuals to make informed decisions about smoking." Pub. L. No. 98-474, § 2, 98 Stat. at 2200. To that end, Congress updated and replaced the prior warning with a rotating set of the following four statements:

> SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, and May Complicate Pregnancy.
>
> SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health.
>
> SURGEON GENERAL'S WARNING: Smoking By Pregnant Women May Result in Fetal Injury, Premature Birth, And Low Birth Weight.
>
> SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide.

Id. § 4, 98 Stat. at 2202. These warnings, known as "the Surgeon General's warnings," have not changed in 40 years.

Recognizing that, in the intervening decades, the Surgeon General's warnings had become "ineffective in providing adequate warnings about the dangers of tobacco products," Congress decided to "require[] stronger and more specific health warnings" through the TCA. H.R. Rep. No. 111-58, at 4 (2009). The TCA required FDA, within 24 months, to "issue regulations that require color graphics depicting the negative health consequences of smoking," which would "accompany" the "label statements" contemplated by the statute. Pub. L. No. 111-31 § 201(d) (codified at 15 U.S.C. § 1333(d)[1]).[1] Congress also authorized FDA to change the label requirements—including the "text" of the label statements—through rulemaking, if FDA found "that such a change would promote greater public understanding of the risks associated with the use of tobacco products." 15 U.S.C. § 1333(d)[1]. Congress further specified that the warnings "shall comprise the top 50 percent of the front and rear panels" of any cigarette package and "at least 20 percent of the area of the advertisement," and set typographical and layout requirements for the warnings, *id.* § 1333(a)(2), (b)(2). It also required that the warnings be randomly displayed in equal numbers on each cigarette brand and that they be rotated quarterly in advertisements. *Id.* § 1333(c)(1)-(2).

II. REGULATORY BACKGROUND

a. After the TCA was enacted, FDA, as directed by Congress, first promulgated a set of nine graphic images to accompany each label statement through regulations issued on June 22, 2011. *See* 76 Fed. Reg. 36,628 (June 22, 2011). In addition to the label statement-image pairs, "FDA also required each graphic image to bear the phone number of the National Cancer Institute's 'Network of Tobacco Cessation Quitlines,' which uses the telephone portal '1-800-QUIT-NOW.'" *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1209 (D.C. Cir. 2012) (quoting 76 Fed. Reg. at 36,681). The 2011 rule was invalidated by the D.C. Circuit. The panel majority concluded that FDA's objective in issuing the rule was reducing smoking rates—rather than informing consumers about the health risks of

[1] As the Court may recall, two provisions of the TCA were codified as 15 U.S.C. § 1333(d). To avoid confusion, this brief (as in the prior briefing) refers to those provisions as §§ 201(a) and 202(b) of the TCA and will cite those provisions as § 1333(d)[1] and § 1333(d)[2], based on the order in which they appear in the statute.

smoking—and held that because the record did not demonstrate that the rule would result in meaningful behavioral change, it did not directly advance the government's interest. *Id.* at 1219.

b. After the D.C. Circuit's decision, FDA began a years-long process to develop new health warnings. The agency targeted a different goal, one derived directly from the text of the TCA: promoting greater public understanding of the negative health consequences of smoking. *See* 15 U.S.C. § 1333(d)[2] (authorizing FDA to adjust the "text of any of the label requirements" upon a finding that the change "would promote greater public understanding of the risks associated with the use of tobacco products"). To ensure any new warnings furthered that goal, FDA embarked on an iterative process for developing, testing, and selecting health warnings. That process began with a "careful[] review [of] the scientific literature on the health risks associated with cigarette smoking," 85 Fed. Reg. at 15,658, which found that "consumers are largely unaware of the negative health consequences of cigarette smoking not mentioned in current warnings as well as more specific information about the negative health effects and their mechanisms." Proposed Rule, 84 Fed. Reg. 42,754, 42,766 (Aug. 16, 2019). FDA followed that with a series of qualitative studies, *i.e.*, informal interviews and focus groups, to gather further input on public awareness of the health risks of smoking and to gauge initial participants' responses to the TCA statements and revised FDA warning statements. *Id.* at 42,767. The qualitative feedback generally indicated that FDA's revised statements did a better job of presenting new information than the TCA statements. Considering that feedback, FDA identified 15 revised statements for further testing. *Id.*

FDA then conducted a large consumer research study (the "first quantitative study"), with 2,505 participants, "to assess which, if any, of 15 revised warning statements would promote greater public understanding" of health risks as compared to the TCA statements. 85 Fed. Reg. at 15,658. That goal was to identify warning statements to be paired with images for FDA's second quantitative study. The first quantitative study found that 10 of the 15 revised statements performed better than the TCA statements in improving understanding. *See* 84 Fed. Reg. at 42,768. So FDA selected those 10 statements, along with 5 from the TCA, to pair with images for further testing. *See id.* at 42,769.

At the same time, FDA was also engaged in an iterative process to develop photorealistic images to be paired with those statements. FDA "consulted the medical literature and . . . medical experts to identify common, visual presentations of each health condition described by the textual warning statements." 85 Fed. Reg. at 15,661. FDA then refined or eliminated images after another series of qualitative interviews. Ultimately, these parallel efforts resulted in 16 paired statements and images for FDA to test in its final quantitative study.

That study (the "second quantitative study") included 9,760 participants and was designed "to identify which," if any, of the 16 text-and-image pairings "increase understanding of the negative health consequences of cigarette smoking." *Id.* at 15,658. FDA collected data on 10 different "outcome measures" to assess which warnings would promote greater understanding of health risks. *Id.* at 15,658-59. Of the 10 measures, FDA identified two at the outset—"new information," *i.e.*, whether the warning statement conveyed information that was new to participants, and "self-reported learning," *i.e.*, whether participants reported learning something from the warning—as the key benchmarks for determining what warnings (if any) to select, based on its finding that those metrics were most "predictive of improved understanding." 84 Fed. Reg. at 42,768-69. Before it conducted the study, FDA committed to selecting only those warnings that outperformed Surgeon General's warnings on both of those metrics. *See* 85 Fed. Reg. at 15,658. Thirteen warning statements cleared this bar and were included in FDA's Proposed Rule, and the remaining three were discarded. *Id.* at 15,658. In fact, all 11 of the warnings FDA ultimately selected "outperformed the current Surgeon General's warnings on 8 of the 10 outcome measures." *Id.* at 15,659.

c. FDA issued a Notice of Proposed Rulemaking on August 16, 2019. 84 Fed. Reg. at 42,754. The Proposed Rule detailed FDA's iterative research process—including a comprehensive explanation of the design and findings of the two quantitative studies—and explained how it arrived at the 13 proposed warnings. After extensive public comment, FDA issued the Final Rule on March 18, 2020. FDA selected 11 factual warning statements, all of which relate to health conditions where "the causal link between cigarette smoking and the negative health consequences . . . is rated at the highest level . . . provided" by the Surgeon General. 85 Fed. Reg. at 15,669. Each statement was paired with a

concordant, medically accurate, photorealistic image. *Id.* at 15,708-09 (codified at 21 C.F.R. § 1141.10(a)(1)).[2]

In the Final Rule, FDA meticulously walked through its reasoning for selecting each of the eleven warnings. It explained why its two key outcome measures—"new information" and "self-reported learning"—were appropriate metrics for measuring improved understanding; carefully explained why the evidence supported the conclusion that each warning would promote greater understanding of the harms of smoking; and refuted claims that the warnings were inaccurate or misleading. *Id.* at 15,671-84. FDA provided thorough responses to the public's comments, including to many from the tobacco industry that have reappeared here. The Rule was slated to take effect on June 18, 2021, after a 15-month compliance period. *See id.*

III. PROCEDURAL HISTORY

Plaintiffs—four cigarette manufacturers and five cigarette retailers—filed this action on April 3, 2020, asserting First Amendment challenges to the Rule and the relevant provisions of the TCA and statutory challenges to the Rule under the APA. ECF No. 1. Over the following two years, the Court relied on 5 U.S.C. § 705 to issue ten orders postponing the effective date of the Rule, *see* ECF No. 33, 80, 89, 91, 92, 93, 94, 96, 100, 104, the last nine of which were entered over Defendants' objection. The Court's final § 705 order provided that the effective date of the Rule would be postponed until November 6, 2023. ECF No. 104.

On December 7, 2022, the Court issued an Opinion and Order vacating the Rule on the grounds that it violated the First Amendment. *R.J. Reynolds Tobacco Co. v. FDA*, No. 6:20-cv-00176, 2022 WL 17489170, at *21 (E.D. Tex. Dec. 7, 2022). The Court did "not consider plaintiffs' other claims" under the APA or the TCA. *Id.* The Fifth Circuit reversed on appeal, concluding that the Rule "survive[s] constitutional muster against the First Amendment challenge." *R.J. Reynolds*, 96 F.4th at 888. Specifically, the Fifth Circuit held that the Rule's warnings were "purely factual" and

[2] The final warnings are reproduced on FDA's website. *See* https://www.fda.gov/tobacco-products/labeling-and-warning-statements-tobacco-products/cigarette-labeling-and-health-warning-requirements.

"uncontroversial," and that they "address a legitimate state interest, are justified, and are not unduly burdensome in light of that interest." *Id.* at 887. It then remanded the case to this Court to "consider the merits of the APA challenge." *Id.* at 888.

Plaintiffs then unsuccessfully sought rehearing en banc. The Fifth Circuit's mandate issued in May 2024, and proceedings restarted in this Court. Rather than proceeding to the merits of the APA challenge to obtain a prompt ruling on the validity of the Rule, Plaintiffs chose to ask the Court to stay further proceedings while they sought review at the Supreme Court. ECF No. 114. Over FDA's objection, *see* ECF No. 115, the Court granted that request. ECF No. 116. On November 25, 2025, the Supreme Court denied Plaintiffs' petition for a writ of certiorari. By an agreement between the parties, FDA will not enforce the Rule against any of the Plaintiffs in this case for a period of fifteen months after the denial of Plaintiffs' petition for a writ of certiorari.

Now, approaching five years since the Rule was promulgated, more than a year after the Court's last postponement of the effective date expired, and more than six months after the Fifth Circuit remanded for consideration of Plaintiffs' APA claims, Plaintiffs now seek an eleventh "postponement" of the effective date. In a sentence, Plaintiffs also request an administrative stay of the Rule "while the Court considers Plaintiffs' postponement motion." Pls.' Mot. to Postpone the Rule's Effective Date 2, ECF No. 122 (Pls.' Mot.).

LEGAL STANDARDS

Under the APA, FDA's "action[s], findings, and conclusions" must be upheld unless they are "arbitrary, capricious, an abuse of discretion, . . . [or] in excess of statutory jurisdiction, authority, or limitation." 5 U.S.C. § 706(2). Judicial review of agency actions under the arbitrary-and-capricious standard is deferential. Courts "should not substitute [their] own judgment for the agency's." *Gulf Restoration Network v. U.S. Dep't of Transp.*, 452 F.3d 362, 368 (5th Cir. 2006). Deference is particularly warranted here because courts "are at [their] most deferential in reviewing the agency's findings" when the "agency's particular technical expertise is involved." *Medina Cnty. Envtl. Action Ass'n v. Surface Transp. Bd.*, 602 F.3d 687, 699 (5th Cir. 2010). Indeed, in the specific "context of a challenge to the FDA's decisionmaking," courts should "give[] a high level of deference' to the agency's scientific

analysis of the evidence before it, and must avoid 'unduly second-guess[ing] [those] scientific judgments." *Pharm. Mfg. Research Servs., Inc. v. FDA*, 957 F.3d 254, 262 (D.C. Cir. 2020) (citations omitted); *see also* Pub. L. No. 111-31, § 2(44), 123 Stat. at 1780 (finding that FDA has "the scientific expertise . . . to evaluate the impact of labels, labeling, and advertising on consumer behavior in order to . . . promote understanding of the impact of the product on health").

Plaintiffs' motion for relief under § 705 of the APA is assessed under the same standard as the "extraordinary and drastic remedy" of a preliminary injunction, *Anibowei v. Morgan*, 70 F.4th 898, 902 (5th Cir. 2023) (citation omitted); *see also Fed'n of Ams. for Consumer Choice, Inc. v. U.S. Dep't of Labor*, No. 6:24-cv-163, 2024 WL 3554879, at *9 (E.D. Tex. July 25, 2024). Courts consider the movant's likelihood of success on the merits, the potential irreparable harm to the movant in the absence of a stay, the harm to the opposing party, and the public interest. *Nken v. Holder*, 556 U.S. 418, 434 (2009). The latter two factors "merge" when the Government is the opposing party. *Id.* at 435. Plaintiffs bear the burden of establishing each factor. *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008).

ARGUMENT

I. FDA COMPLIED FULLY WITH THE APA IN PROMULGATING THE RULE.

A. The Rule is not arbitrary and capricious.

Plaintiffs' primary submission has always been that the Rule violates the First Amendment. The Fifth Circuit has now squarely rejected that claim. Undeterred, Plaintiffs now seek to enlist what used to be a tacked-on and conclusory arbitrary-and-capricious claim under the APA as a vehicle to resuscitate and relitigate their failed First Amendment arguments. *See* Pls.' Mot. at 9-20. Sometimes they move a few words around, sometimes they don't—but the arguments have not materially changed, despite their rejection by the Fifth Circuit. A few examples:

First Amendment Section of Plaintiffs' Fifth Circuit Brief	Arbitrary-and-Capricious Section of Plaintiffs' District Court Motion
Page 48: Most significantly, the Rule lacks any evidence demonstrating that the warnings will further FDA's only asserted interest: "promot[ing] greater public understanding" of smoking risks. 84 Fed. Reg. at 42,755.	**Page 10**: Here, the Rule lacks evidence that the warnings will further FDA's only asserted interest: "promot[ing] greater public understanding" of particular smoking risks, 84 Fed. Reg. at 42,755.

Page 35: As a result, the public already knows that smoking is harmful.	**Page 11**: As a result, the public already knows that smoking is harmful.
Page 36: The public also knows about the major risks of smoking.	**Page 11:** The public also knows about the major risks of smoking.
Page 36-37: FDA tries to sidestep this problem by claiming that the warnings address "less known health consequences of smoking." This is fundamentally flawed . . . . (citations omitted).	**Page 11:** FDA tries to sidestep this problem by claiming that the warnings address "less-known health consequences of smoking." 84 Fed. Reg. at 42,756-57. This is fundamentally flawed . . . .
Page 39: [FDA's first quantitative study] also showed that many of the FDA-created textual warnings were not believable	**Page 12**: FDA's studies showed that many of the FDA-created textual warnings were not believable.
Page 24: And—although not designed to target this issue—*FDA's own studies* demonstrated that consumers will take away misleading and inaccurate messages from the Rule's images and text.	**Page 14**: Finally, although not designed to target this issue, FDA's own studies demonstrated that consumers would take away misleading and inaccurate messages from the Rule's images and text.
Page 24: Indeed, the reactions of study participants confirm that *every* graphic warning will mislead, confuse, or shock consumers.	**Page 15:** Indeed, the reactions of study participants confirm that *every* graphic warning will mislead, confuse, or shock consumers.
Page 25: In short, it is no surprise that, as the district court held, "each of the graphic warnings" can be reasonably interpreted to convey inaccurate meanings.	**Page 15**: It is thus no surprise that this Court found that "each of the graphic warnings" can be reasonably interpreted to convey inaccurate meanings.
Page 43: First, the government could find alternative ways of delivering the information—such as by increasing its own anti-smoking speech (or funding for anti-smoking programs and advertising by third parties).	**Page 18**: Most obviously, the government could find alternative ways of delivering the information—such as by increasing its own anti-smoking messaging (or funding for anti-smoking programs and advertising by third parties).
Page 45: The district court was also correct that FDA failed to consider the potential efficacy of less-burdensome warnings. For instance, FDA could change the warnings' text, location, and/or size. But FDA never even considered these options and instead simply assumed that bigger is better—an approach that would equally justify warnings that take up 90% of cigarette packaging. (citation omitted)	**Page 18**: This Court was also correct that FDA failed to consider the potential efficacy of less burdensome warnings. For instance, FDA could change the warnings' text, location, and/or size. But FDA never even considered these options and instead relied on generic conclusions that bigger is better—an approach that would equally justify warnings that take up 90% of packaging. (citation omitted)
Page 45: The record reflects that several of these readily available less-restrictive alternatives would likely have been effective.	**Page 19**: The record reflects that several of these readily available less-restrictive alternatives would likely have been effective.

This chart could have been far longer. But these representative examples amply demonstrate that Plaintiffs' arbitrary-and-capricious theory is a thinly disguised reprise of the First Amendment arguments that the Fifth Circuit has already rejected.

In a sense, this was unavoidable—because Plaintiffs have always recognized that their First Amendment and arbitrary-and-capricious arguments would rise and fall together. In the Fifth Circuit, Plaintiffs flatly asserted that the Rule violates the APA "for the same reasons it fails First Amendment review." Resp. Br. for Appellees at 48 (5th Cir. July 12, 2023). In this Court, Plaintiffs likewise argued that "the Rule fails under [APA] standards for all of the same reasons it fails First Amendment review." Pls.' MSJ at 49, ECF No. 34. But now that those "same reasons" have been rejected by the Fifth Circuit in the context of the First Amendment, those "same reasons" also fail under the APA. The Court needs to say little more than that to dispose of Plaintiffs' arbitrary-and-capricious claim.

Of course, Defendants acknowledge that, as a matter of appellate procedure, the Fifth Circuit remanded the APA claims to this Court. Nonetheless, that the Fifth Circuit rejected often-verbatim arguments under the First Amendment should, at the very least, heavily inform this Court's analysis of those same arguments under the APA. As a practical matter, it is difficult to imagine a scenario in which the Rule is sufficiently "well justified" to satisfy constitutional scrutiny under the First Amendment, *R.J. Reynolds*, 96 F.4th at 884, but is also, simultaneously, so unreasonable as to violate "the APA's deferential arbitrary-and-capricious standard." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 417 (2021); *cf. United States v. Pineiro*, 470 F.3d 200, 205 (5th Cir. 2006) ("When on remand the district court assays to implement the mandate, it must proceed within the letter and spirit of the mandate by taking into account the appeals court's opinion and the circumstances it embraces.").[3]

In any event, the Fifth Circuit was correct to conclude that the Rule was "well justified," *R.J. Reynolds*, 96 F.4th at 884, and to reject all of Plaintiffs' arguments to the contrary. Because FDA's "analysis was reasonable and reasonably explained," *Prometheus Radio Project*, 592 U.S. at 426, Plaintiffs' arbitrary-and-capricious claim lacks merit.

[3] The Solicitor General's statement that at least some of Plaintiffs' arguments "would be better considered under the rubric of the APA," Pls.' Mot. at 8 (quoting U.S. Br. in Opp'n to Cert. at 17, 26), does not suggest that those arguments have any merit, or that they are consistent with the Fifth Circuit's opinion (which binds this Court, but not the Supreme Court).

1. FDA "well justified" the Rule based on robust scientific evidence in the rulemaking record. *R.J. Reynolds*, 96 F.4th at 884.

Many of Plaintiffs' arbitrary-and-capricious arguments boil down to the assertion that FDA's empirical studies were not perfect, or that some of the data were capable of other interpretations. But "[t]he APA imposes no general obligation on agencies to conduct or commission their own empirical or statistical studies" at all, *Prometheus Radio Project*, 592 U.S. at 427—much less requires perfect studies that examine every conceivable issue in bottomless depth. Ultimately, after cherry-picking snippets of data out of context and quibbling with minutiae of study design, Plaintiffs do little more than insist that FDA "did not have perfect empirical or statistical data" before it acted to carry out Congress's command. *Id.* But "that is not unusual in day-to-day decisionmaking within the Executive Branch," *id.*, and it offers no basis for a finding that the Rule is arbitrary and capricious under the APA.

a. Plaintiffs assert that the Rule is unnecessary because "the public already knows the risks of smoking." Pls.' Mot. at 10. The macabre irony of that argument warrants brief acknowledgment—as, for decades, several of these Plaintiffs intentionally misled their own customers and the public about those very risks. *See, e.g.*, *Philip Morris*, 566 F.3d at 1121 (per curiam) ("28 years after Reynolds scientists declared the presence of carcinogenic compounds in cigarettes was 'now well established,' a Reynolds press release and newspaper advertisement declared the connection between smoking and disease 'an open controversy.'"). In any event, Plaintiffs made this argument to the Fifth Circuit, *see supra* at 11, which rejected it: "[T]hat people already know smoking is dangerous does not mean that they know all the health consequences of smoking." *R.J. Reynolds*, 96 F.4th at 885 n.71. That conclusion was sound, as multiple studies show that "consumers are largely unaware of the negative health consequences of cigarette smoking not mentioned in the current warnings as well as more specific information about the negative health effects and their mechanisms." 84 Fed. Reg. at 42,766. That is why the Rule is "focused on less-known health consequences of smoking." *Id.* at 42,756-57.

Plaintiffs then retreat to the narrower claim that six of the Rule's eleven warnings allegedly "describe well-known risks," and thus are unnecessary. Pls.' Mot. at 11-12 (emphasis omitted). As an initial matter, that means Plaintiffs concede that the public lacks sufficient information about the five

other health consequences the warnings address—namely, that smoking causes bladder cancer, reduces blood flow (which can cause erectile dysfunction), causes type 2 diabetes, causes cataracts (which can lead to blindness), and reduces blood flow to the limbs (which can require amputation).

For the remaining six, Plaintiffs' argument suffers from an overarching flaw: a failure to even mention, much less dispute, the results of FDA's second quantitative study. Those results demonstrate that a significant percentage of respondents found all eleven warnings—including the six about health consequences that Plaintiffs claim are well known—to provide new information, suggesting that Congress and FDA were correct to conclude that the public is not adequately informed. *Cf. Flyers Rts. Educ. Fund Inc. v. U.S. Dep't of Transp.*, 957 F.3d 1359, 1363 (D.C. Cir. 2020) (emphasizing that a determination as to whether a given "quantum of evidence of consumer confusion . . . warrants a rulemaking falls within [an agency's] discretion"). Specifically, the results for each of the warnings that Plaintiffs single out are as follows:

- **"Tobacco smoke can harm your children."** This warning was reported to be new information by 40.7% of participants who viewed it. 85 Fed. Reg. at 15,671.
- **"Tobacco smoke causes fatal lung disease in nonsmokers."** This warning was reported to be new information by 41.9% of participants who viewed it. *Id.* at 15,672-73.
- **"Smoking causes head and neck cancer."** This warning was reported to be new information by 80.9% of participants who viewed it. *Id.* at 15,673-74.
- **"Smoking can cause heart disease and strokes by clogging arteries."** This warning was reported to be new information by 52.1% of participants who viewed it. *Id.* at 15,677.
- **"Smoking during pregnancy stunts fetal growth."** This warning was reported to be new information by 40% of participants who viewed it. *Id.* at 15,676.
- **"Smoking causes COPD, a lung disease that can be fatal."** This warning was reported to be new information by 35.7% of participants who viewed it. *Id.* at 15,678.

Additionally, each of these warnings outperformed the current Surgeon General's warnings, to a statistically significant degree, on at least seven other measures that bear on the extent to which the warnings promote understanding. *See id.* at 15,671-78. Plaintiffs provide no basis for questioning the accuracy of these results. Nor do Plaintiffs provide a reason to ignore the results of FDA's rigorous quantitative study in favor of the other data they cite. *See* Pls.' Mot. at 11-12. Many of those

citations rest on apples-to-oranges comparisons, like Plaintiffs' attempt to elevate the results of FDA's first qualitative study, which used different stimuli, did not involve images, and featured only 146 participants, over FDA's second quantitative study, which included nearly 10,000 participants and tested image-text pairings. *See* AR 23288-89. Given the findings of FDA's second quantitative study, FDA had more than enough evidence to reasonably conclude that the warnings would better promote understanding of all eleven of the negative health consequences that FDA selected.

b. Plaintiffs note that "FDA conducted just two quantitative studies to support its asserted interest," Pls.' Mot. at 10—although that is two more than necessary under the APA, *Prometheus Radio Project*, 592 U.S. at 427. Plaintiffs then assert that the quantitative studies are "deeply flawed" because FDA's samples were not nationally representative. Pls.' Mot. at 10. But that charge fails to engage with FDA's thorough discussion of this issue in the Rule. As the agency explained, "an experimental design does not require a nationally representative sample to demonstrate a valid and reliable effect." 85 Fed. Reg at 15,663; *see also id.* (the agency set "specific recruitment targets for the number of study participants in each age group and tobacco-use category to be recruited into the study population"). All studies require tradeoffs in their design and execution, and FDA's selection of participants was reasonable and consistent with best scientific practices. *See* AR 54055 (Peer Review Report) (finding that FDA's selection of the "study population represents a good trade off" because although the sample is not nationally representative, it is "diverse," "easily recruitable," and "appropriate to address the research questions"). Regardless, FDA's acknowledgment of and response to this criticism is enough to satisfy the APA, even if reasonable minds could differ on FDA's approach.

Plaintiffs also suggest that FDA's studies did not demonstrate "*meaningful* gains in consumers' knowledge" because FDA used the current Surgeon General's warnings as the control condition. Pls.' Mot. at 14. But Plaintiffs fail to propose a different control, and FDA's methodological choice is supported by the record. *See* AR 54070 (Peer Review Report) (explaining that "the current standards for warnings" were "an appropriate control group[]" for the second quantitative study). Additionally, Plaintiffs do not contest the agency's findings that—in absolute terms—a large percentage of study participants reported that the eleven warnings were new information. *See* 85 Fed. Reg. at 15,655

(warnings provided new information to between 35.7% and 88.7% of study participants). It is not clear what more Plaintiffs are looking for. Regardless, the fact that FDA and cigarette companies looked at the same "studies" but "interpreted them differently" is neither surprising, nor an APA problem. *Prometheus Radio Project*, 592 U.S. at 426.

c. Plaintiffs say they fear "that consumers would take away misleading and inaccurate messages from the Rule's images and text." Pls.' Mot. at 14. Before the Fifth Circuit, Plaintiffs likewise argued "that the updated textual warnings create Warnings that 'misleadingly exaggerate smoking risks' and improperly 'focus on conditions that less frequently arise from smoking'" in a way that would confuse consumers. *R.J. Reynolds*, 96 F.4th at 879. And Plaintiffs also emphasized then, as they do now, that "this Court found that 'each of the graphic warnings' can be reasonably interpreted to convey inaccurate meanings." Pls.' Mot. at 15 (quoting Op. & Order at 31, ECF No. 106).

These arguments cannot survive the Fifth Circuit's opinion. The very same analysis that Plaintiffs now elevate, the Fifth Circuit described as "error." *R.J. Reynolds*, 96 F.4th at 881. For example, Plaintiffs maintain that FDA was limited to selecting a warning image "depicting the most common result" of each health condition. *See* Pls.' Mot. at 15 (quoting Op. & Order at 30). But the Fifth Circuit "uncover[ed] no caselaw requiring the government to choose only the most common side-effect or consequence of the disease or injury discussed in a warning." *R.J. Reynolds*, 96 F.4th at 881. Instead, "[a]s FDA points out, it would 'not [be] feasible . . . for a single warning to convey all the information that may be related to a particular health condition.'" *Id.* at 881 n.56 (quoting 85 Fed. Reg. at 15,684). Ultimately, faced with the same arguments that Plaintiffs now advance, the Fifth Circuit held (1) that "the factual content of the warnings is undisputed," and (2) that "[t]he images are no different from those a medical student might see in a textbook." *Id.* at 879-80. There is no basis for this Court to second-guess FDA's scientific judgments or the Fifth Circuit's conclusions about whether the warnings are "misleading," "inaccurate," or "confusing." Pls.' Mot. at 14-15.

d. Plaintiffs also take issue with some of the measures FDA selected to assess whether the warnings it tested will, in fact, promote understanding about smoking's health risks. Although FDA collected data on ten measures, it determined that two particular measures—whether a warning was

"new information" and whether participants learned something ("self-reported learning")—were the best predictors of improved understanding. 85 Fed. Reg. at 15,658. FDA selected these measures for three principal reasons. First, to *understand* a risk, a consumer must be aware of it, and the record established that the "new information" measure helps target areas of knowledge where there are "opportunities to improve understanding through increased awareness." 84 Fed. Reg. at 42,769. Second, the record also reflects that "people are more likely to pay attention to information that is new, and attention plays a vital role in message comprehension and learning." *Id.* Third, FDA reasonably concluded that other possible measures, such as "thinking about the risks" or "health beliefs," were not likely to change after participants had only limited exposure to the warnings. *Id.*

Notably, FDA prioritized these two measures *before* it conducted the study, leaving itself no wiggle room in the event the warnings performed poorly. The agency determined that "individual warnings *must* demonstrate statistically significant improvements, as compared to the control condition, on both the two outcomes of New Information and Self-Reported Learning" to be eligible for inclusion as final warnings. AR 50772 (emphasis added).[4]

In any event, Plaintiffs' critique of FDA's measures falls short. For starters, Plaintiffs (still) do not dispute that "new information" and "self-reported learning" are, as FDA found, measures that encapsulate a necessary component of understanding a message. *See* 84 Fed. Reg. at 42,769. Moreover, although Plaintiffs disparage them as "non-standard measures of questionable validity," Pls.' Mot. at 13, the record shows that FDA "was guided by communication and social science theories" in selecting them. AR 39705;[5] *see also id.* (citing support in the literature for selection of "new information" and "self-reported learning" as measures of understanding). Indeed, several peer reviewers expressly endorsed the agency's choice of the outcomes it measured. *See* AR 54097, 54105 (Peer Review Report). Where, as here, "specialists express conflicting views, an agency must have

[4] Experimental Study of Cigarette Warnings, FDA Supporting Statement Part A, 2019.

[5] Experimental Study of Cigarette Warnings: Study 2 Report, 2020 ("Revised Second Quantitative Report").

discretion to rely on the reasonable opinions of its own qualified experts even if, as an original matter, [the reviewing court] might find contrary views more persuasive." *Medina Cnty.*, 602 F.3d at 699.

Plaintiffs next contend that FDA should not have used "new information" and "self-reported learning" as its key metrics, because those measures capture an *initial* step in the process of understanding a message, rather than the entire process. *See* Pls.' Mot. at 13. But Plaintiffs conflate the role of these two measures—which is to be "*predictive* for promoting understanding of the risks associated with cigarette smoking"—with the goal of the warnings themselves—which is to actually promote that understanding. 85 Fed. Reg. at 15,658-59 (emphasis added). FDA "prioritize[d] the outcomes that provide the best assessment of initial reactions" because "more 'delayed' outcomes . . . are unlikely to change after only brief exposure to a warning." *Id.* at 15,662. In other words, measuring an early indicator of understanding makes sense in the context of a study with a limited time horizon. And again, decisions regarding "methodology and data analysis" fall squarely within "the agency's technical expertise." *Kennecott Greens Creek Min. Co. v. MSHA*, 476 F.3d 946, 956 (D.C. Cir. 2007).

Even if Plaintiffs could overcome the high bar necessary to set aside FDA's selection of "new information" and "self-reported learning" as the most predictive measures, there would be no basis for upsetting the agency's conclusion that the final warnings promote understanding of smoking's negative health consequences. That is because all eleven warnings also "surpassed the Surgeon General's warnings on six *other* measures"—specifically, the warnings "led to more thinking about risks; were higher on perceived informativeness, perceived understandability, and perceived helpfulness [in] understanding health effects; attracted more attention; and were better recalled." 85 Fed. Reg. at 15,658 (emphasis added). Those findings put to rest Plaintiffs' remaining concerns.

The only measures on which the final warnings were not across-the-board better than the Surgeon General's warnings are "perceived factualness" and "health beliefs." While Plaintiffs thus dwell on these two measures, *see* Pls.' Mot. at 12-13, nothing about them changes the reasonableness of the agency's bottom-line conclusions. In fact, that the 40-year-old Surgeon General's warnings generally outperformed the final warnings on the "perceived factualness" measure is fully consistent with the conclusion that the final warnings are better at promoting greater public understanding. As

FDA explained, it "is common in pre-implementation studies that test warnings about health effects for which there are low levels of consumer awareness" for those warnings to test comparatively poorly on measures of perceived factualness. 85 Fed. Reg. at 15,660 (citing comment from Professor David Hammond, located at AR 28785). That stands to reason, as the literature on this issue confirms: "individuals presented with new information may view it with skepticism and even consider the new information less factual than information they have seen before." *Id.* In other words, the very reason these warnings are needed—*i.e.*, because of their "'novelty' or newness," *id.* at 15,663—is a reason they may not *seem* as factual as the Surgeon General's warnings to a study participant.

That leaves "health beliefs" as the measure on which Plaintiffs must hang their critique of FDA's second quantitative study. Plaintiffs assume, without citing any evidence in the record, that "altering participants' beliefs about smoking risks" is "the best measurement of whether the warnings would promote greater public understanding of [the] risks" FDA selected. Pls.' Mot. at 6. Plaintiffs then take that assumption and try to redefine the goals of FDA's research, suggesting that FDA expected to find that the warnings "chang[ed] study participants' beliefs" about smoking and "moved the goalposts" when that result did not come to pass. *Id.* at 10, 12.

That narrative is false. FDA selected "new information" and "self-reported learning" as the make-or-break measures for the warnings *before* it conducted the second quantitative study. *See* AR 50772 (FDA Study Supporting Statement). And FDA did *not* expect "health beliefs" to change significantly because such a result is "unlikely . . . after only brief exposure to a warning." 85 Fed. Reg. at 15,662. Plaintiffs do not contest that conclusion, suggesting instead that FDA should somehow have "design[ed] a longer-term study." Pls.' Mot. at 12. But they point to no evidence indicating what such a study might have looked like, much less show that FDA was unreasonable in choosing a more feasible methodological approach.

In any event, Plaintiffs' focus on "health beliefs" overlooks that the warnings performed remarkably well on that measure. Nine of the final eleven warnings "demonstrated statistically significant improvements over the Surgeon General's warnings between Session 1 of the study and Session 2," and six of the final eleven warnings "demonstrated statistically significant improvements

over the Surgeon General's warnings" between Session 1 and Session 3, even though Session 3 was approximately 17 days later. 85 Fed. Reg. at 15,659. To put that in perspective, six of the warnings were so effective at changing participants' health beliefs that the effects still lingered, to a statistically significant degree, more than two weeks after just "two brief exposures" to the warnings. *Id.* Plaintiffs cite no research indicating that FDA could, or should, have hoped for the warnings to perform better.

e. Finally, Plaintiffs describe FDA's first and second quantitative studies as "self-contradictory." Pls.' Mot. at 14. This is a fitting critique on which to close because it illustrates many of the flaws that plague Plaintiffs' failure to carefully engage with FDA's research. For instance, it shows how Plaintiffs target other portions of the record as a roundabout way of calling into the question the key portion—*i.e.*, FDA's second quantitative study. For although Plaintiffs apply the "self-contradictory" label to *both* quantitative "studies," they cite data from only the *first,* which tested only text statements, without images (whereas the second study tested the image-text pairings in the Proposed Rule). *See id.* In addition, the argument rests on the alleged identity between a "new information" measure and an "informative[ness]" measure. *See id.* But the measures are different. Whereas "new information" reflects the knowledge that participants reported gaining, "informativeness" gauges participants' subjective assessment of the warning—specifically, whether participants "*considered* the [FDA-generated] statement to be more informative." AR 10863, 10868 (emphasis added). It is not contradictory—in fact, it is unsurprising—that participants would report learning more new information from a warning they nonetheless *perceived* to be less informative, because "[w]hen individuals are presented with new information, this new information may be viewed with skepticism and perceived as less factual than information that is familiar or well-known." 85 Fed. Reg. at 15,663. Plaintiffs, once again, ignore FDA's careful analysis.

Ultimately, Plaintiffs provide no reasoned basis to question that the second quantitative study's "consistent pattern of findings for each individual required warning *and* across all the required warnings is highly supportive" of FDA's conclusion that the eleven final warnings promote understanding of the negative health consequences of smoking. *Id.* at 15,660. That failure is even more pronounced considering the deference owed to FDA in its exercise of scientific expertise. FDA

set out to determine whether its proposed warnings further the interest the government advances in this litigation—an interest that the Fifth Circuit has now endorsed as "legitimate, and substantial." *R.J. Reynolds*, 96 F.4th at 885. For the eleven warnings the agency selected, the answer was an unequivocal yes. There is no basis to disturb that reasoned judgment.

2. FDA considered all important aspects of the problem.

a. Plaintiffs contend that "FDA ignored whether the Rule would help people quit smoking, which is an important aspect of the analysis" under the APA. Pls.' Mot. at 16. But as explained in the Rule, FDA "does not agree with comments asserting that the Agency's one true interest lies in reducing smoking rates." 85 Fed. Reg. at 15,644; *see also id.* at 15,660 ("[T]he Government's interest in this rule is not to reduce smoking rates, but rather it is to promote greater public understanding of the negative health consequences of smoking."). Instead, as the Fifth Circuit correctly understood, "FDA justified the Warnings through an informational interest, specifically focusing on raising consumer awareness," *R.J. Reynolds*, 96 F.4th at 884—not based on a desire to reduce smoking.

Before the Fifth Circuit, Plaintiffs insisted that FDA's informational interest "is insufficient because it does not address any real-world problems (such as smoking rates)." Resp. Br. of Appellees at 38. The Fifth Circuit disagreed, concluding that "FDA has sufficiently proven that the Warnings reasonably relate to and further its legitimate, and substantial, interest" in promoting greater understanding of the health risks of smoking. *R.J. Reynolds*, 96 F.4th at 885. In short, "that people already know smoking is dangerous does not mean that they know all the health consequences of smoking," which means that "[i]nforming them of those is a legitimate state interest." *Id.* at 885 n.71; *accord Disc. Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509, 519 (6th Cir. 2012) (holding that "warning the general public about the harms associated with the use of tobacco products" is "a significant interest"). The basic premise of Plaintiffs' argument—that smoking rates must always be the critical metric—is both unsupported, and irreconcilable with the Fifth Circuit's opinion.

Cigar Association of America v. FDA, 964 F.3d 56 (D.C. Cir. 2020), is not to the contrary. There, the D.C. Circuit interpreted a separate provision of the TCA that explicitly directs FDA to consider "the increased or decreased likelihood that existing users of tobacco products will stop using such

products" in promulgating certain requirements. 21 U.S.C. § 387f(d)(1). In interpreting that provision as applied to FDA warnings for cigars and pipe tobacco, the D.C. Circuit observed that the statute directed FDA to consider "whether the warnings will actually affect product usage." *Cigar Ass'n*, 964 F.3d at 62. Plaintiffs' argument elides the fact that an entirely different provision of the TCA governs here, *see* 15 U.S.C. § 1333(d)[1]. And unlike for regulations issued under § 387f(d)(1), Congress chose *not* to make the issuance of cigarette health warnings contingent on findings about smoking rates; instead, it expressly focused FDA's attention on whether the warnings will "promote greater public understanding of the risks associated with the use of tobacco products." 15 U.S.C. § 1333(d)[2]. FDA made that information-related finding.

b. Plaintiffs next protest that "FDA failed to consider the emotional impact of the warnings." Pls.' Mot. at 17. Yet again, that premise is hard to square with the Fifth Circuit's opinion, which held that "[t]he Warnings are both factual and uncontroversial, despite the emotional impact the graphics may have." *R.J. Reynolds*, 96 F.4th at 875. Indeed, as the Fifth Circuit explained, "emotional response to a statement is *irrelevant* to its truth." *Id.* at 880 (emphasis added). And in the specific context of this Rule, "at most, the emotional response of viewers is *incidental* to their retention of information about the health risks." *Id.* (emphasis added). Plaintiffs never acknowledge these conclusions from the Fifth Circuit, nor explain why they think "the emotional impact of the warnings" is "an important aspect of the problem" at all. Pls.' Mot. at 17. It is not, as the Fifth Circuit's opinion effectively confirms.

In any event, even if emotion were an important aspect of the problem, that wouldn't matter here—because it is untrue that "FDA failed to consider the emotional impact of the warnings." *Id.* In fact, FDA devoted almost two-thousand words to this subject. *See* 85 Fed. Reg. at 15,645-47. Some commenters argued that the warnings "are intended to convey emotions of fear, shame, and disgust," or that "the point of the warnings is to force consumers to look at gruesome images that evoke feelings of shame and fear." *Id.* at 15,645. FDA considered the matter, and expressly "disagree[d] with those comments that suggest[ed] the visual depictions are not factual and accurate based on their assertion that they are designed to evoke an emotional response." *Id.* at 15,645-46. FDA explained its view that, "[i]n general, the possibility that factual content may evoke an emotional reaction does not render

the content less factual," and thus any incidental emotional response would not undermine the appropriateness of these warnings. *Id.* at 15,646. Given that explanation, Plaintiffs are simply mistaken to suggest that FDA "entirely failed to consider" this subject in the Rule. *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Were there any doubt, the Fifth Circuit necessarily recognized as much when it *agreed* with FDA's conclusion that "the emotional impact of the Warnings does not abrogate their factual nature." *R.J. Reynolds*, 96 F.4th at 880.

3. FDA considered and rejected less burdensome alternatives.

Again reprising one of their unsuccessful First Amendment theories, Plaintiffs maintain that FDA failed to consider or justify less burdensome alternatives—including several that would have deviated sharply from Congress's explicit instructions in the TCA itself—such as "text-only warnings; smaller, differently placed warnings; or a public-information campaign." Pls.' Mot. at 18. In any event, the Fifth Circuit already held that "the Warnings are not unduly burdensome" with respect to constitutional limits, *R.J. Reynolds*, 96 F.4th at 886, and the Rule likewise survives deferential APA review. In short, both Congress and FDA reasonably determined that warnings like these are necessary, and there is no basis for this Court to second guess that determination.

a. Plaintiffs primarily take issue with the size of the warnings (50% of the front and back of cigarette packages, 20% of advertisements) and their placement at the top of packages and advertisements. Pls.' Mot. at 17-19. Those requirements, however, come directly from the TCA, 15 U.S.C. § 1333(a)(2), (b)(2), and it is squarely within Congress's "traditional legislative authority to make predictive judgments when enacting nationwide regulatory policy." *Turner Broad. Sys., Inc. v. FCC*, 520 U.S. 180, 196 (1997). Accordingly, on top of the usual APA deference to reasonable agency policy choices, additional "deference must be accorded to [Congress's] findings as to the harm to be avoided and to the remedial measures adopted for that end." *Id.* It is the rare APA plaintiff that sues the government on the theory that the agency should have *ignored* Congress's instructions. Indeed, Defendants are aware of "no authority to support a finding that [an agency] violated the APA where the [agency] did what Congress said it could do." *Florida v. Buttigieg*, --- F. Supp. 3d ----, 2024 WL 4536647, at *16 (S.D. Fla. Sept. 27, 2024), *appeal pending*, No. 24-12261 (11th Cir. Oct. 7, 2024).

Deference is particularly appropriate here because Congress is not new to the business of requiring health warnings on cigarettes. Congress first required such warnings in 1965, *see* Pub. L. No. 89-92, modified them in 1970, Pub. L. No. 91-222, updated them in 1984 in light of a need to make Americans "more aware of any adverse health effects of smoking," Pub. L. No. 98-474, § 2, and revamped them once more in 2009 through the TCA. Congress knows how to draw reasonable lines with respect to such warnings, and it knows whether its prior efforts have achieved their desired ends. *See Schirmer v. Edwards*, 2 F.3d 117, 122 (5th Cir. 1993) (upholding the Louisiana legislature's decision to double the "campaign-free zone" around polling locations after an earlier law proved "inadequate"). And here, the question is not whether to mandate warnings at all—Plaintiffs concede that the Surgeon General's Warnings are lawful. *See* Compl. ¶ 1. Rather, the question is about the precise specifications for the revised warnings. Because "the agency has acted within a zone of reasonableness" by following Congress's instruction, there is no basis for the Court to "substitute its own policy judgment" about the optimal size and placement of the warnings. *Prometheus Radio Project*, 592 U.S. at 423.

The Fifth Circuit, for its part, had no concerns with the size and placement of the warnings in the context of Plaintiffs' First Amendment claim—in which Plaintiffs advanced more-or-less the same arguments. In rejecting these arguments, the Fifth Circuit emphasized that "these Warnings are no larger than those upheld by the Sixth Circuit when it reviewed the TCA," and that FDA has "not changed the size of the Warnings" in light of Congress's directive. *R.J. Reynolds*, 96 F.4th at 885 (citing *Discount Tobacco*, 674 F.3d at 567). In addition, "plaintiffs can still speak on 80% of their advertisements, and they still control more than 50% of the total surface area of their cigarette packages." *Id.* at 886. Quoting from FDA's record-based findings, the Fifth Circuit thus agreed that "[t]he remaining portions offer 'ample room for manufacturers to distinguish their products from other products.' 85 Fed. Reg. at 15,647." *Id.*

The Fifth Circuit (unlike Plaintiffs) did not second-guess FDA's findings that "the Warnings directly alleviate information asymmetry regarding the harms tobacco causes and consumers' sub-optimal awareness of and response to those harms." *Id.* Because "the government has shown a significant benefit from the resultant reduction in those harms," the "scale tilts towards the benefits."

Id. Accordingly, after expressly considering the size and placement of the warnings, the Fifth Circuit concluded that "the Warnings are not unduly burdensome" under the First Amendment. *Id.*

The same result holds for the APA version of these arguments—if anything, with greater force in light of FDA's record-based findings and Congress's explicit instructions. In short, FDA found that "the scientific literature strongly supports that larger warnings, such as those of the size proposed in this rule, are necessary to ensure that consumers notice, attend to, and read the messages conveyed by the warnings[.]" 85 Fed. Reg. at 15,650-51. FDA also found that "placement of the warnings at the top 50 percent of the front and rear panels of the packages and at least the top 20 percent of advertisements will better ensure noticeability of the warnings." *Id.* at 15,651. Plaintiffs challenge none of these record-based findings—they simply pretend they don't exist, asserting incorrectly and without elaboration that "FDA never even considered" the option of "less-burdensome warnings." Pls.' Mot. at 18. And they repeatedly rely on this Court's prior conclusions that, for example, "the government has not shown that compelling these large, graphic warnings is necessary in light of other options." *Id.* (quoting Op. & Order at 33). But, respectfully, the Fifth Circuit reversed, so reliance on that analysis confirms that Plaintiffs' arbitrary-and-capricious claim fails—to use Plaintiffs' words—"for all of the same reasons" as their First Amendment claim did. Pls.' MSJ at 49, ECF No. 34.

b. Plaintiffs likewise assert that FDA "ignored" the possibility of text-only warnings. Pls.' Mot. at 17. Again, Plaintiffs are mistaken. *See* 84 Fed. Reg. at 42,762-65; 85 Fed. Reg. at 15,648. Setting aside whether FDA had the authority to issue text-only warnings, *see* Pls.' Mot. at 19-20, FDA also rejected that option for reasons of science and policy. In short, "the scientific literature strongly supports that pictorial cigarette warnings promote greater public understanding about the health consequences of smoking," because they "increase knowledge and learning of the negative health consequences of smoking," and "benefit subpopulations that have disparities in knowledge about" those consequences. 85 Fed. Reg. at 15,648. Among other things, FDA considered the value of images with respect to the wide variability in the public's ability to read and understand health information, 84 Fed. Reg. at 42,769-70, and to communicate information to youth, *id.* at 42,764. FDA did not need to add yet another study to confirm what the literature already reflects. So the Court

need not decide whether—as Plaintiffs only halfheartedly suggest, *see* Pls.' Mot. at 19-20—FDA could have dismissed Congress's explicit directive that it "require color graphics depicting the negative health consequences of smoking to accompany the label statements." 15 U.S.C. § 1333(d)[1].[6]

c. Plaintiffs also suggest that FDA should have *entirely* discarded Congress's mandate for new warnings and instead pursued only "a public-information campaign." Pls.' Mot. at 18. But FDA already conducts such campaigns. *See, e.g.*, FDA's Youth Tobacco Prevention Plan, *available at* https://www.fda.gov/tobacco-products/youth-and-tobacco/fdas-youth-tobacco-prevention-plan. As FDA explained, although "voluntary public education campaigns can provide effective targeting and messaging, they do not reach every person who looks at a package of cigarettes or advertisements and do not receive as many impressions as a comprehensive program of cigarette package and cigarette advertisement warnings." 85 Fed. Reg. at 15,648. And the decision to ensure that every person who picks up a pack of cigarettes be informed of the negative health consequences of smoking reflects a decades-long policy judgment by Congress. *See id.* The wisdom of that decision was confirmed by the research FDA performed in support of the Rule, which found that "pictorial cigarette warnings placed directly on products convey the risks to those who look at packages and advertisements with more immediacy and noticeability." *Id.* In light of this evidence, FDA's conclusion that public health campaigns were not a sufficient substitute for pictorial health warnings "was reasonable and reasonably explained." *Prometheus Radio Project*, 592 U.S. at 426.[7]

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[6] The same is true with respect to Plaintiffs' other arguments about alternatives that are undisputedly inconsistent with the TCA. *See* Pls.' Mot. at 17-20. Because FDA in fact considered and rejected those alternatives, this Court need not opine on the outer bounds of FDA's authority to modify "any of the label requirements" in the statute. 15 U.S.C. § 1333(d)[2]. Even so, the government's position that it may adjust the default text of the warning statements, through rulemaking, in some circumstances, *see infra* at 38-40—a power explicitly granted by Congress in 15 U.S.C. § 1333(d)[2]—does not inexorably lead to the conclusion that FDA is also permitted to discard the entire concept of text-image warning pairs, or throw out the warnings altogether in favor of a public-information campaign. In any event, none of those broader questions are presented here.

[7] Briefly, Plaintiffs also suggest that "FDA provided no rational explanation for rejecting" a "nine-warnings option" that would have been "less costly" than the Final Rule. Pls.' Mot. at 20. But FDA explained at length in the Final Rule (and Defendants have explained at length in this brief) why all eleven of the warnings that FDA chose further Congress's and FDA's shared goal of promoting

In sum, FDA appropriately balanced Congress's judgment, the scientific literature, and the findings of its own studies on the degree to which the final warnings promote understanding of the harms of smoking. Although it is not surprising that Plaintiffs would prefer that FDA simply ignore the TCA, it was not arbitrary and capricious for FDA to follow Congress's instructions.

4. FDA reasonably responded to comments.

Plaintiffs briefly point to two alleged deficiencies in FDA's response to comments. First, they claim that "FDA provided no meaningful response to criticisms based on its qualitative studies." Pls.' Mot. at 21. That is wrong. FDA explained the limited role that it gave to the qualitative studies in its iterative process, acknowledging that they were "based on small sample sizes" and "do not yield data that can be generalized." 85 Fed. Reg. at 15,666. For those reasons, although FDA used the qualitative studies to help "test and refine" the warning statements and "obtain feedback on which pairings of textual warning statements and images should be selected for further study," it did not place any additional reliance on those studies. *Id.*

Second, Plaintiffs assert that FDA "ignored criticisms from its own peer reviewers." Pls.' Mot. at 22. But the only specific point that Plaintiffs claim went unaddressed is the selection of measures for FDA's quantitative studies—an issue that FDA amply addressed and that Defendants have already discussed at length. *See supra* at 17-18 (support in the literature and from peer reviewers).

5. Plaintiffs cannot challenge the reasonableness of FDA's cost-benefit analysis.

Plaintiffs contend that FDA acted unreasonably because, in a cost-benefit analysis of the Rule, FDA "cho[s]e to describe the benefits [of the Rule] qualitatively," instead of numerically monetizing those benefits. Pls.' Mot. 21. That argument suffers from at least three key flaws.

First, whether an agency's cost-benefit analysis is reviewable under the APA depends on the text of the authorizing statute. *Michigan v. EPA*, 576 U.S. 743, 752 (2015) (statutory language requiring

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greater public understanding of the health risks of smoking. *See supra.* And Plaintiffs' objection that FDA "has never quantified the Rule's purported benefits," Pls.' Mot. at 20, is just a rehash of its meritless argument about FDA's approach to cost-benefit analysis. *See infra* at 27-29.

agency find that regulation was "appropriate and necessary" mandated "at least some attention to cost"); *Am. Textile Mfrs. Inst., Inc. v. Donovan*, 452 U.S. 490, 510 (1981) ("When Congress has intended that an agency engage in cost-benefit analysis, it has clearly indicated such intent on the face of the statute."). The TCA imposes no obligation to conduct a cost-benefit analysis at all, and thus "the agency was not required [by statute] to undertake a cost-benefit analysis" here. *Nicopure Labs, LLC v. FDA*, 266 F. Supp. 3d 360, 400-01 (D.D.C. 2017), *aff'd*, 944 F.3d 267 (D.C. Cir. 2019).[8]

Second, contrary to Plaintiffs' suggestion, FDA did not invoke its cost-benefit analysis as a justification for the Rule, *see* Pls.' Mot. at 21, but simply reported the results of the analysis required by "[Executive Orders] 12866 and 13563," 85 Fed. Reg. at 15,697—both of which expressly preclude judicial review, *see* Exec. Order No. 12,866 § 10, 58 Fed. Reg. 51,735 (Sept. 30, 1993); Exec. Order No. 13,563 § 7(d), 76 Fed. Reg. 3,821 (Jan. 18, 2011); *Nat'l Truck Equip. Ass'n v. NHTSA*, 711 F.3d 662, 670 (6th Cir. 2013) ("Executive Order 12,866 does not create judicially enforceable rights, nor does it provide a basis for rejecting final agency action."); *Air Transp. Ass'n of Am. v. FAA*, 169 F.3d 1, 8-9 (D.C. Cir. 1999) (holding challenge to cost-benefit analysis under EO 12,866 was "not subject to judicial review," rejecting plaintiff 's argument that "it does not seek to assert rights under the order but is merely referencing it to provide evidence of the arbitrary and capricious nature of the . . . decision," and calling it "nothing more than an indirect—and impermissible—attempt to enforce private rights under the order"). Thus, there is no basis for APA review of that analysis here.

Third, even if reviewable, FDA's analysis was reasonable. Plaintiffs cannot meaningfully dispute that there are benefits to the Rule. As the Fifth Circuit recognized, FDA "has shown a significant benefit from" the Rule's alleviation of the "information asymmetry regarding the harms tobacco causes and consumers' sub-optimal awareness of and response to those harms." *R.J. Reynolds*,

[8] The cases Plaintiffs rely on are not to the contrary. *See Chamber of Com. v. SEC*, 85 F.4th 760, 772 (5th Cir. 2023) (statute required agency to "consider or determine whether an action is 'necessary or appropriate in the public interest'" (quoting 15 U.S.C. § 78c(f)); *Mex. Gulf Fishing Co. v. U.S. Dep't of Com.*, 60 F.4th 956, 966 (5th Cir. 2023) (statute authorized regulation "only if it is necessary and appropriate, which at a minimum requires that its benefits reasonably outweigh its costs"); *see also Sw. Elec. Power Co. v. EPA*, 920 F.3d 999, 1019 (5th Cir. 2019) (discussing the unobjectionable, and inapposite, principle that an agency acts arbitrarily and capriciously if it fails to explain its rationale).

96 F.4th at 886. Instead, Plaintiffs complain about the way in which FDA analyzed those benefits. But the Fifth Circuit has held that agencies are not "required to undertake a quantitative analysis to determine" the economic implications of a regulation, and that "[i]t is within the agency's discretion to determine the mode of analysis that most allows it to determine as best it can the economic implications of the rule it has proposed." *Chamber of Com.*, 85 F.4th at 760, 773. Here, FDA explained that there was a "high level of uncertainty" in how to monetize the benefits of greater public understanding of the health risks of smoking. AR 39629; *see also Chamber of Com. v. SEC*, 115 F.4th 740, 755 (6th Cir. 2024) ("The value of informed decisionmaking is not a benefit that can be readily quantified, but instead lends itself to a qualitative analysis."). The agency accordingly used a "per-package break-even estimate," which it found would help "decision-makers to understand the magnitude of non-quantified benefits." AR 39630-31. Consistent with the Fifth Circuit's decision in *Chamber of Commerce*, that choice was well within FDA's discretion. *See Sinclair Wyoming Refin. Co. v. EPA*, 101 F.4th 871, 889 (D.C. Cir. 2024) (Where "it would be infeasible to monetize the benefits" of a rule, a "quantitative cost-benefit analysis can be misleading, because the calculation of new benefits does not provide a full evaluation of all relevant benefits and costs" (cleaned up)); *Inv. Co. Inst. v. CFTC*, 720 F.3d 370, 379 (D.C. Cir. 2013) (agency's "discussion of unquantifiable benefits fulfills its statutory obligation to consider and evaluate potential costs and benefits"); *Nicopure*, 266 F. Supp. 3d at 406 (upholding FDA's use of break-even analysis where it "provided substantial detail on the benefits of the rule, and the reasons why quantification was not possible").

FDA's approach was particularly sound because the TCA charges FDA with "promot[ing] greater public understanding" of the health risks of smoking. 15 US.C. § 1333(a)(1), (d)[2]. In other words, Congress made a policy choice that the informational benefits from new, more effective warnings justified imposing the costs of compliance on tobacco manufacturers and retailers. Plaintiffs cannot fault FDA for "the fact that the statute Congress drafted is designed to yield benefits that it deemed important but understood are not easily monetizable." *Sinclair*, 101 F.4th at 889. That the benefits of the Rule "are not easily monetizable does not mean they are less valuable." *Id.*

B. FDA complied with the APA's notice-and-comment requirements.

The APA's notice-and-comment procedures require only that the agency issue a "[g]eneral notice of proposed rulemaking" and offer "interested persons an opportunity to participate through submission of written data views or arguments." *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96 (2015) (quoting 5 U.S.C. §§ 553(b), (c)). The Supreme Court has held that § 553 "established the maximum procedural requirements which Congress was willing to have the courts impose upon agencies in conducting rulemaking procedures." *Vt. Yankee Nuclear Power Corp. v. Nat. Res. Def. Council, Inc.*, 435 U.S. 519, 524 (1978). Plaintiffs advance two procedural arguments based on these notice-and-comment requirements. First, they assert that "FDA failed to provide meaningful notice" because its publication of certain studies in connection with the Proposed Rule—including hundreds of pages of reports summarizing and analyzing those studies—did not also include all the underlying raw data from each study. *See* Pls.' Mot. 22-24. Second, they argue that FDA's 15-day extension of the initial 60-day comment period was too short. *Id.* at 24. Both arguments are meritless.

1. FDA had no obligation to publish all the raw data from all its studies with its "general notice of proposed rulemaking."

The APA requires that an agency provide a "*[g]eneral* notice of proposed rule making" that sets forth "either the terms or *substance* of the proposed rule or a *description* of the *subjects* and issues involved." 5 U.S.C. § 553(b)(3) (emphases added). Interested parties must be provided an opportunity to "participate meaningfully" in the rulemaking process. *Chamber of Com.*, 85 F.4th at 779. The touchstone is whether interested persons are "'fairly appris[ed] . . . of the subjects and issues the agency [is] considering.'" *Huawei Techs. USA, Inc. v. FCC*, 2 F.4th 421, 448 (5th Cir. 2021) (quoting *Chem. Mfrs. Ass'n v. EPA*, 870 F.2d 177, 203 (5th Cir. 1989)).

There is little doubt that interested parties were fairly apprised about FDA's qualitative and quantitative studies, sufficient to allow them to meaningfully comment on the adequacy, rigor, and reliability of FDA's studies. In the Proposed Rule, FDA provided a detailed description of the research, evidence, assumptions, and methodology underlying its conclusions that the proposed warnings would promote greater public understanding of the health consequences of smoking. 84

Fed. Reg. 42,759-72. FDA (1) summarized the state of scientific literature on the ineffectiveness of the Surgeon General's warnings and the potential for updated, more noticeable warnings to promote public awareness of smoking's risks, *id.* at 42,759-65; (2) described in detail the quantitative and qualitative studies that it carried out to inform and develop its proposed warnings—including explanations of the studies' designs, methodology, key data, and findings, *id.* at 42,765-72; and (3) presented its proposed new warnings and explained the scientific bases for its conclusions that each of the proposed warnings would promote greater public awareness of the risks of smoking, *id.* at 42,772-77. On top of these detailed and lengthy explanations, FDA also published detailed reports, comprising hundreds of pages, summarizing its two quantitative studies, and cited 220 publicly available sources (including peer-reviewed journal articles, congressional findings and reports, and Surgeon General's reports). *See id.* at 42,789-96. In addition, FDA also later published additional reports, also comprising hundreds of pages, about its qualitative studies and reopened the comment period for 15 more days to allow comments on those reports, *see id.*[9]

As is typical, FDA did not immediately publish all the raw data sets for each of its studies. Those data sets have now been provided to Plaintiffs as part of the administrative record, for which the standard is broader. *See, e.g.*, *Optimus Steel, LLC v. U.S. Army Corps of Eng'rs*, No. 1:20-cv-00374, 2020 WL 13042508, at *1 (E.D. Tex. Sept. 22, 2020) ("all documents and materials directly or indirectly considered by agency decision-makers" (citation omitted)).

Plaintiffs latch onto the prior nondisclosure of the raw data underlying FDA's studies to suggest that they lacked a meaningful opportunity to comment. But "while interested parties should be able to participate meaningfully in the [rulemaking] process, the public 'need not have an opportunity to comment on every bit of information influencing an agency's decision.'" *Chamber of Com.*, 85 F.4th at 779 (quoting *Tex. Off. of Pub. Util. Couns. v. FCC*, 265 F.3d 313, 326 (5th Cir. 2001)).

[9] Though Plaintiffs sometimes imply that FDA "fail[ed] to release these reports" at all, Pls.' Mot. 23, that is incorrect. To clarify, by November 12, 2019, FDA had published detailed reports—and provided an opportunity to comment—on all the relevant studies. *See* 84 Fed. Reg. 42,779 (NPRM Refs. 129 and 153); 84 Fed. Reg. 60,966, 60,968 (Nov. 12, 2019) (qualitative study reports).

The APA requires only a "[g]eneral notice" of "either the terms or the substance" of the proposed rule or "a description of the subjects and issues" involved, 5 U.S.C. § 553(b)(3), and makes no mention of studies or data. Plaintiffs' attempt to impose a requirement that *all* raw data be produced *before* the comment period does not square with Fifth Circuit precedent or the settled rule that courts may not require more of agencies than the APA explicitly provides for. *Vt. Yankee*, 435 U.S. at 524.

Although courts have sometimes required that an agency solicit comments on key *reports* about studies "that served as the technical basis for [a] rule," *Texas v. EPA*, 389 F. Supp. 3d 497, 503-06 (S.D. Tex. 2019) (requiring disclosure of "Final Connectivity Report," as it was among "the most critical factual materials used to support the Final Rule," but making no mention of underlying data), the Fifth Circuit has rejected claims, like Plaintiffs', that a meaningful opportunity to comment requires that an agency make available all potentially relevant underlying *data*—particularly where, as here, the agency summarized the data and provided an opportunity to comment on the study reports.

In *Chemical Manufacturers*, the plaintiffs argued that the EPA violated the APA's notice-and-comment requirements "by relying on economic data . . . that were never made available to the public for comment." 870 F.2d at 200. The Fifth Circuit found that there was no error because the notice of proposed rulemaking had "adequately advised interested parties of the method the EPA had followed, the financial data it proposed to rely on, and its intention to develop an economic-impact study"—even though the data remained undisclosed. *Id.* at 201-02; *see also Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1212-13 (5th Cir. 1991) (agency "probably did not violate the notice requirement of 5 U.S.C. § 553" even though it "failed to give notice to the public . . . that it intended to use 'analogous exposure' data to calculate the expected benefits of certain product bans," but invalidating regulation for substantive reasons under a different statute); *Aqua Slide 'N' Dive Corp. v. Consumer Prod. Safety Comm'n*, 569 F.2d 831, 842 (5th Cir. 1978) (similar).

Rather than grappling with Fifth Circuit precedent, Plaintiffs rely on an overreading of out-of-circuit authorities, none of which holds that an agency's otherwise robust disclosures about studies violate the APA if all underlying raw data is not disclosed. Pls.' Mot. 23. These cases require the notice of proposed rulemaking contain "sufficient factual detail and rationale for the rule to permit

interested parties to comment meaningfully," *Nat'l Lifeline Ass'n v. FCC*, 921 F.3d 1102, 1115 (D.C. Cir. 2019)—not *everything* that was before the agency. *Accord Mo. Limestone Producers Ass'n v. Browner*, 165 F.3d 619, 622 (8th Cir. 1999) (agency was "not required to provide detailed factual data" to support action where it "included a lengthy description of the substance and purpose" of the action).[10]

FDA satisfied that obligation by disclosing the qualitative and quantitative study reports. Those reports distilled, summarized, and analyzed the studies' assumptions and methodological choices, the relevant data, and FDA's conclusion from that data. Those reports provided more than enough information about the studies for interested parties to analyze and comment on any supposed shortcomings therein. The peer reviewers—experts in the field—certainly thought the reports disclosed enough information. Each of the reviewers was asked whether they were provided "sufficient information . . . about the study design, stimuli, sample, methods, analysis, and results," AR 54047, and none raised any concerns with the amount of data that had been provided, let alone requested *any* of the raw data, *see, e.g.*, AR 54071, AR 54077, AR 54088, AR 54102; *see also Huawei*, 2 F.4th at 448 (agency provided adequate opportunity to comment where notice enabled interested party to comment on "those aspects of the final rule it claims were not properly noticed"); *United Steelworkers of Am., AFL-CIO-CLC v. Schuylkill Metals Corp.*, 828 F.2d 314, 318 (5th Cir. 1987) (citing comments

[10] *See, e.g.*, *N. Am.'s Bldg. Trades Unions v. OSHA*, 878 F.3d 271, 301 (D.C. Cir. 2017) (stating in dicta that an agency should "identify and make available *technical studies and data* that it has employed in reaching the decisions to propose particular rules," but declining to reach a holding because any error had been rendered harmless by subsequent publication of the data for comment and concluding that OSHA's "fail[ure] to disclose the basis for" certain "assumptions" underlying its decision did not provide "grounds for questioning OSHA's conclusion that [it] provided the best available evidence" during the comment period); *Kern Cnty. Farm Bureau v. Allen*, 450 F.3d 1072, 1076, 1080 (9th Cir. 2006) (citing similar D.C. Circuit dicta about disclosure of "the technical basis for a proposed rule," but holding that, the agency "was not required to reopen the public comment period" where studies conducted post-comment period confirmed information previously disclosed prior to comment period); *see also Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 239 (D.C. Cir. 2008) (finding agency erred where it conducted reports about studies but only "place[d] the *redacted*" versions of those reports "in the rulemaking record," and the court concluded that "the unredacted portions [we]re likely to contain evidence that could call into question the Commission's decision to promulgate the rule").

by interested parties on disputed issue as evidence that agency provided adequate opportunity to comment). Plaintiffs had access to all the same information.[11]

Plaintiffs' additional claim that they lacked an opportunity to comment on the peer review analyses of the two quantitative studies, Pls.' Mot. 23, also misses the mark. The peer review report was prepared by external experts who, like Plaintiffs, were reviewing material that FDA had published on the rulemaking docket. The APA mandates that interested parties have an opportunity to comment on the *agency's proposal*, not on *other comments to* the agency's proposal. Plaintiffs cite nothing for the proposition that an agency violates the APA's notice-and-comment requirements if it does not solicit another round of comments about prior comments already received. "Were it otherwise, an agency could find itself stuck in an infinite feedback loop of public comment on response to public comments." *Alaska v. Lubchenco*, 825 F. Supp. 2d 209, 224 (D.D.C. 2011).

2. FDA's supplemental 15-day comment period was sufficient.

The original comment period on the Proposed Rule was 60 days—the typical length for FDA rules. *See* 21 C.F.R. § 10.40(b)(2). Plaintiffs do not contend that was insufficient time to comment. Rather, they argue that the 15-day supplemental comment period that FDA provided after publishing four qualitative study reports was too short. Pls.' Mot. 24.

The APA, however, "does not specify a minimum time for submission of comments in informal rulemaking," *Petry v. Block*, 737 F.2d 1193, 1201 (D.C. Cir. 1984), and courts generally lack the authority to arbitrarily impose a minimum required length for a comment period, *see Phillips Petroleum Co. v. EPA*, 803 F.2d 549, 559 (10th Cir. 1986) (citing *Vt. Yankee*, 435 U.S. at 543). Though

[11] Plaintiffs also try to make hay from an FDA memorandum that noted that publishing raw study data could allow third parties to analyze it in "selective, biased, or misleading ways." Pls.' Mot. 24. But that is irrelevant because FDA satisfied the APA's requirements by providing sufficient opportunity to comment on the studies. In any event, Plaintiffs' selective quotation ignores the portions of the memorandum that undermine their position. *See, e.g.*, AR 23863.1 ("[T]he raw data are not necessary for replicating the studies or evaluating the adequacy or scientific rigor of FDA's consumer research."); AR 23863.2 ("Because the themes and feedback from the qualitative studies were comprehensively summarized in the study reports, the verbatim transcripts are not needed to meaningfully comment on the adequacy or scientific rigor of the qualitative studies.").

Plaintiffs cite authorities for the proposition that, under certain circumstances, a fifteen-day *primary* comment period could be insufficient, Pls.' Mot. 24, none of those cases impose any limitation on a *supplemental* comment period. Here, FDA provided 15 additional days, on top of a 60-day comment period, for interested parties to comment on just *four new documents*. *See* 84 Fed. Reg. at 60,967-68 (reopening comment period "to allow comment on the additional materials"). Plaintiffs do not explain why—given the narrow set of materials that were the subject of the supplemental comment period, the original 60-day comment period, and Plaintiffs' extensive familiarity with the relevant issues under the TCA—15 days was insufficient time to comment on the qualitative study reports. *See, e.g.*, *Omnipoint Corp. v. FCC*, 78 F.3d 620, 629-30 (D.C. Cir. 1996) (rejecting challenge to seven-day comment period in light of "congressional mandate" to move quickly and the fact that interested parties already had some knowledge of forthcoming rulemaking); *Conn. Light & Power Co. v. Nuclear Reg. Comm'n*, 673 F.2d 525, 534 (D.C. Cir. 1982) (30-day primary comment period was reasonable where agency had engaged with "members of the industry for over five years"). Indeed, it was not, as Plaintiffs had ample time to submit a lengthy supplemental comment. *See* AR 36856.[12]

3. Any notice-and-comment error was harmless.

Even if there were any violation of the APA's notice-and-comment requirements, Plaintiffs fail to show prejudice. The APA requires that "due account shall be taken of the rule of prejudicial error," 5 U.S.C. § 706, and procedural errors that do not cause "substantial prejudice" are to be excused, *Chem. Mfrs.*, 870 F.2d at 202. "[T]he burden of showing that an error is harmful normally falls upon the party attacking the agency's determination." *Shinseki v. Sanders*, 556 U.S. 396, 409 (2009).

Defendants are aware that the Fifth Circuit has recently said that "the harmless error rule is quite narrow." *Wages & White Lion Inv., LLC v. FDA*, 90 F.4th 357, 389 (5th Cir. 2024), *cert. granted*, 144 S. Ct. 2714 (2024). That assertion is in tension with the Supreme Court's instruction that the APA

[12] FDA's decision to provide 15 days for additional comments was made in part to ensure compliance with a court order from separate litigation, which required FDA to submit the Final Rule for publication in the Federal Register no later than March 15, 2020. *Am. Acad. of Pediatrics v. FDA*, No. 1:16-cv-11985-IT, 2019 WL 1047149, at *3 (D. Mass. Mar. 5, 2019). In light of that order, it was especially important that FDA minimize unnecessary delay.

incorporated "the same kind of 'harmless-error rule that courts ordinarily apply in civil cases," *Sanders*, 556 U.S. at 406, under which the court must assess "the likelihood that the result would have been different," *id.* at 411; *see also Ohio v. EPA*, 144 S. Ct. 2040, 2057 (2024) (harmless error asks whether the agency "would have reached the same conclusions" without the error). Notably, the Supreme Court granted the government's petition for a writ of certiorari in *Wages & White Lion*. But even under the standard from *Wages & White Lion*, this Court should still find the harmless-error rule applies here, as Plaintiffs cannot show any prejudice from any of the alleged procedural errors.

With respect to the disclosure of FDA's raw study data, as discussed above, during the rulemaking FDA disclosed comprehensive study reports, which provided more than enough detail for interested parties to analyze and comment on the adequacy and reliability of the studies. *See Chem. Mfrs.*, 870 F.2d at 202 (declining to find substantial prejudice from agency's "use of undisclosed supplementary economic data"). Despite having had the underlying raw data as part of the administrative record in this litigation for more than four years, Plaintiffs (still) have never contended that the quantitative study reports failed to accurately summarize the raw data or that FDA's conclusions from the raw data reflected any data or calculation errors. Rather, their critiques of the quantitative studies rest on complaints about the studies' design, sample, methodologies, and outcome measures—all of which were fully disclosed to Plaintiffs at the start of the initial comment period. The fact that Plaintiffs continue to be unable to use the underlying raw data to support their substantive arguments against the Rule is a powerful indicator that they suffered no prejudice from not having the data before the comment period. *See Air Transp. Ass'n of Am. v. U.S. Dep't of Agric.*, 37 F.4th 667, 677 (D.C. Cir. 2022) (any hypothetical error arising from agency's reliance on unreleased information was harmless where plaintiffs offered no arguments that were "substantively different than the arguments made prior to the receipt of this information").

Nor did Plaintiffs suffer prejudice from the nondisclosure of the transcripts underlying the qualitative studies. The qualitative study reports disclosed the exact sorts of stray statements from focus group members that Plaintiffs unconvincingly cite as evidence of supposed confusion generated by the proposed warnings. *See* Pls.' Mot. at 3-4 (relying on statements from disclosed qualitative study

reports). Plaintiffs point generally to statements they compiled in an appendix, *id.* at 25, but they do not specify which, if any, statements matter, and in any event, those statements offer nothing that readers of the study reports were not already aware of. Moreover, in their comment to the Proposed Rule, Plaintiffs *already* argued that the warnings were confusing, misleading, and provoked negative emotions. *See* AR 27484 (comment asserting that the proposed warnings "evoke negative emotions, such as fear, shame and disgust" and contending that FDA's second quantitative study "confirm[ed]" that warnings would not promote knowledge because of negative emotions); AR 27494-95 (arguing that the proposed warnings "are inaccurate or misleading," and "exaggerate the effects of the disease the purport to represent, exaggerate the likelihood of those diseases being caused by smoking, or offer a misleading portrayal of the treatment of those diseases"). There is no reason to believe that additional, isolated focus group observations that were cumulative of the points Plaintiffs already made would have had any bearing on FDA's decisionmaking process.

Plaintiffs next argue that the disclosure of the raw data could have allowed them to assess issues "that FDA has failed to adequately explain" in the Rule. Pls.' Mot. 26. At best, that is an (unpersuasive) argument that the Rule is arbitrary and capricious for lack of a reasoned explanation, not a notice-and-comment violation. In any event, Plaintiffs have now had the underlying data as part of the administrative record for almost half a decade and have been free to use it to assess FDA's explanation of the Rule. That they still have not done so is telling.

Plaintiffs' claim of prejudice from the inability to comment on the peer review analyses is even more tenuous. Plaintiffs contend that had they been able to comment on the peer review analyses, they "could then have explained" those supposed criticisms to FDA. *Id.* But FDA reviewed and considered the peer review analyses *themselves*. There is no prejudice stemming from Plaintiffs' inability to parrot back the peer review analyses to FDA. And they do not suggest what more they would have said on the subject that FDA should have considered.

Finally, Plaintiffs cannot identify any prejudice from the length of the 15-day supplemental comment period. As noted above, Plaintiffs (and others) actually submitted another round of lengthy comments during that additional comment period. *See, e.g.*, AR 36856, 36886, 36889, 36943

(supplemental comments of RAI Services, Marissa G. Hall, *et al.*, Altria, and Professor Hammond); *see also Fla. Power & Light Co. v. United States*, 846 F.2d 765, 772 (D.C. Cir. 1988) ("no evidence that petitioners were harmed by the short comment period" where agency received extensive comments anyway). Though Plaintiffs suggest that they could have "deepen[ed]" their arguments for why the proposed warnings were misleading or provoked negative emotions, they do not explain why that "deepening" could not have been accomplished within 15 days and still do not identify what more, if anything, they would have said with more time. *See, e.g.*, *Air Transp. Ass'n of Am. v. Civil Aeronautics Bd.*, 732 F.2d 219, 224 n.11 (D.C. Cir. 1984) (error harmless where plaintiff "does not explain what it would have said had it been given earlier access to the staff studies"). And, as discussed, Plaintiffs and others made these very same arguments about the supposed shortcomings of the proposed warnings in their original and supplemental comments. *See, e.g.*, AR 36903-04 (comment from Altria arguing that "FDA's supplemental materials bolster concerns that the proposed warnings are misleading").

II. THE RULE IS AUTHORIZED BY THE TOBACCO CONTROL ACT.

In the TCA, Congress authored a set of default textual warning statements. *See* 15 U.S.C. § 1333(a)(1). Then, in a provision titled "Change in Required Statements," it expressly authorized FDA to "adjust the format, type size, color graphics, and text of any of the label requirements," so long as the change is carried out "through a rulemaking" and FDA "finds that such a change would promote greater public understanding" of the health risks of smoking. *Id.* § 1333(d)[2]. FDA has done both. Nevertheless, Plaintiffs argue that the Rule violates the TCA because it increases the total number of warning statements from nine to eleven and because (in Plaintiffs' view) FDA's authority to alter the label requirements "kicks in only *after* FDA" first issues an initial rule using the default warning statements. Pls.' Mot. 27-28. Neither argument has merit.

a. The plain text of the TCA authorizes FDA to add warning statements. Section 202(b) permits FDA to change "*any* of the label requirements." 15 U.S.C. § 1333(d)[2] (emphasis added). "Read naturally, the word 'any' has an expansive meaning, that is, one or some indiscriminately of whatever kind." *United States v. Gonzalez*, 520 U.S. 1, 5 (1997) (citation omitted). Nothing in the TCA

restricts that broad conferral of authority by preventing the addition of new warnings. Nor does anything in the text of the TCA specify a total of nine, and only nine, warning labels. Thus, Plaintiffs cannot point to anything in the text that suggests that Congress silently prohibited the addition of new or modified warnings as part of its broad delegation of authority to FDA.

Plaintiffs' atextual reading of § 202(b) is also dispelled by § 202(a) of the TCA, which amended the Labeling Act's preemption provision to provide that "[e]xcept to the extent the Secretary requires *additional* or *different* statements on any cigarette package by a regulation," no statement beyond those required by statute "shall be required on any cigarette package." 15 U.S.C. § 1334(a) (emphases added). The TCA's reference to "additional or different statements" is irreconcilable with Plaintiffs' reading of the TCA as (silently) mandating nine-and-only-nine statements. Plaintiffs suggest that § 202(a) should be read to apply only to some narrower class of disclosures under 15 U.S.C. § 1333(e), Pls.' Mot. at 27, but, here again, they identify no statutory text that limits § 202(a) in that fashion. Courts must "respect not only what Congress wrote but, as importantly, what it didn't write." *Va. Uranium, Inc. v. Warren*, 587 U.S. 761, 766 (2019). Moreover, Congress did not even require disclosures under 15 U.S.C. § 1333(e), making it especially unlikely that Congress (again, silently) intended its reference to "additional or different statements" to reach only a narrow class of theoretical disclosures.

b. Plaintiffs' argument that FDA's modification authority is triggered only after issuance of an initial rule similarly lacks any textual grounding. There is simply no statutory provision that requires FDA to first issue warnings with the Act's default statements, and then wait 15 months or more for such warnings to be implemented, before it can then embark on any effort to revise the warning statements. Rather, Congress conditioned FDA's modification authority under § 202(b) on FDA (1) conducting a rulemaking and (2) making a finding that any changes would promote greater understanding of smoking's health risks—nothing more. *See* 15 U.S.C. § 1333(d)[2].

Plaintiffs point to § 201(a)'s direction to FDA to issue regulations "to accompany the label statements," Pls.' Mot. 27, but nothing in that language imposes Plaintiffs' proposed order of operations. That language does not speak to FDA's authority to modify the warning text under § 202(b), a distinct conferral of authority from § 201(a), let alone stipulating the timing or sequencing

of any modifications. Plaintiffs argue that the reference to "color graphics" in § 202(b) means that § 202(b) requires a preexisting regulation, as FDA could not modify color graphics "before a graphic-warnings rule is promulgated." *Id.* But, again, nothing in § 202(b) mentions timing or sequencing or suggests that FDA must wait until *all* relevant label features—format, type size, color graphics, and text—are specified in an earlier rulemaking before it may adjust *any* of them. The fact that FDA could not change color graphics before a prior rule because there are no default images in the TCA says nothing about whether FDA can change the default textual warnings that do exist.

Finally, Plaintiffs protest that under FDA's reading of § 202(b), FDA "would not be limited to eleven warnings." *Id.* at 27. That is true. But contrary to Plaintiffs' suggestion, FDA could not "dictate as many warnings as it wished," *id.*, because § 202(b) conditions changes to the label requirements on a finding that the changes "would promote greater public understanding" of the health risks of smoking. As detailed above, FDA made that finding here.

III. PLAINTIFFS' REQUEST FOR EMERGENCY RELIEF SHOULD BE DENIED.

There is no reason to grant Plaintiffs' request for a "postponement" of the effective date of the Rule. For starters, there is nothing to postpone—the Rule is already in effect. The Court's last postponement expired on November 6, 2023, and the Fifth Circuit's mandate reversing the Court's judgment was issued on May 29, 2024. Because the Rule has been in effect for months, Plaintiffs' request to "postpone" that date is moot. *See VanDerStok v. Garland*, 633 F. Supp. 3d 847, 863 (N.D. Tex. 2022) (holding that § 705 was "inapposite" where final rule had already gone into effect). But to the extent Plaintiffs are requesting some other form of time-sensitive relief, the Court should deny it. This case can be litigated to a final judgment now, as Defendants have been arguing for months.

A. Plaintiffs' claims of irreparable harm do not justify emergency relief, and this case should be litigated to final judgment.

Plaintiffs do not dispute that the Rule will not be enforced against them until February 2026, at the earliest. Nevertheless, they argue that, absent a stay, they will incur compliance costs imminently, which are unrecoverable if the Rule is invalidated. Pls.' Mot. 28-29. That argument fails to sustain Plaintiffs' request for emergency relief.

Plaintiffs' pronouncements of significant and immediate costs are belied by their tactical choices after remand. In May, Plaintiffs' APA claims were back before this Court, ready to be briefed and decided. If the need for clarity on the Rule's validity were as pressing as Plaintiffs say, there was ample time to brief and resolve Plaintiffs' APA claims—which already had been fully briefed to this Court and the Fifth Circuit—while Plaintiffs sought the longshot of Supreme Court review of their First Amendment claims. Instead, Plaintiffs demurred, hoping to save the effort of preparing briefs and arguing the motion. *See* Pls.' Status Report at 3-4, ECF No. 114. But having affirmatively argued for even more delay, Plaintiffs cannot now turn around and profess an urgent need for extraordinary and time-sensitive relief under § 705. If this truly were an emergency, Plaintiffs have no explanation for why they hit the snooze button for seven months.

Instead, this case should be teed up for final judgment. The parties briefed cross-motions for summary judgment four years ago and intend to do so again. Those cross-motions turn on most of the same legal arguments as Plaintiffs' § 705 motion, and the Court should simply resolve those motions and enter judgment for the prevailing party, as it did last time. ECF Nos. 106-07.[13]

Finally, in a drive-by, Plaintiffs also suggest the Court should issue a temporary administrative stay. Pls.' Mot. 2. Plaintiffs do not explain why a "temporary" freeze on the Rule to "buy[] the court time to deliberate," *United States v. Texas*, 144 S. Ct. 797, 798 (2024) (Barrett, J., concurring), would be justified in these circumstances, where (1) the Rule is already in effect, (2) the Rule will not be enforced against Plaintiffs for at least another fourteen months, and (3) Plaintiffs sought to delay resolution of this case for tactical reasons. Thus, even if a district court has authority to issue an administrative stay without Plaintiffs' making the required showing for preliminary injunctive relief, Plaintiffs have not shown why an administrative stay would be warranted here.

[13] Plaintiffs suggest without elaboration that the Court's prior § 705 rulings—from more than two years ago—are somehow "law of the case." Pls.' Mot. 28. But that makes little sense and would require the Court to turn a blind eye to changed circumstances over the past two years, particularly the Rule going into effect and Plaintiffs' tactical choice to prioritize delay.

B. The public interest disfavors emergency relief.

This lawsuit is only the most recent in a long history of tobacco industry efforts to resist (or at least delay) disclosure of information about their deadly products. This Court should not indulge that project further. "The public interest involved in this dispute" sweeps well "beyond the immediate interests of the named litigants" and includes "the consumers upon whose behalf" Congress and FDA have acted. *Miss. Power & Light Co. v. United Gas Pipe Line Co.*, 760 F.2d 618, 626 (5th Cir. 1985). Generations of Americans, past and present, have been ravaged by nicotine addiction and smoking-related disease, often with an inadequate appreciation of those risks until it was far too late—due in part to deliberate deception by some of these Plaintiffs and their competitors. And an overwhelming majority of those who become addicted to nicotine begin using tobacco products as minors. 21 U.S.C. § 387 note (Legislative Finding 31). Nearly five years ago, FDA issued the Rule to carry out Congress's command in the TCA to require updated disclosures of important information about the dangers of smoking. Yet the American public remains consigned to the stale 40-year-old Surgeon General's warnings that Congress concluded needed changing more than 15 years ago. The Court should decline Plaintiffs' invitation for further delay and should bring this case to a final resolution.

IV. PLAINTIFFS' REQUESTS FOR RELIEF ARE OVERBROAD.

For the reasons set forth above, the Court should deny Plaintiffs' requests for emergency relief and enter summary judgment for Defendants. But if the Court disagrees, Plaintiffs' requested relief—a universal "postponement" of the effective date of the Rule under § 705—is still overbroad. Both the TCA and the Rule contain robust severability clauses, which this Court should respect by severing any unlawful portions while leaving the rest in place—as Congress and FDA plainly intended. In addition, § 705, Article III, and the TCA require that any relief be limited to these Plaintiffs.

A. Any unlawful portions of the Rule should be severed.

The Court should uphold the Rule as lawful. But at an absolute minimum, the Court should decline Plaintiffs' invitation to "postpone" the Rule in its entirety because both the TCA and the Rule itself reflect an intent that any invalid provisions of the Rule be severed. Thus, if the Court were to determine that FDA adequately justified some portions of the Rule but not others—for example,

some but not all warning statements, some but not all images, or the textual warnings but not the images—it should apply the principles of severability.

Typically, "[w]hether the offending portion of a regulation is severable depends upon [1] the intent of the agency *and* [2] upon whether the remainder of the regulation could function sensibly without the stricken provision." *MD/DC/DE Broadcasters Ass'n v. FCC*, 236 F.3d 13, 22 (D.C. Cir. 2001); *accord Sw. Elec. Power Co. v. EPA*, 920 F.3d 999, 1033 (5th Cir. 2019) (vacating only "the portions of the final rule" that the court decided were unlawful). Congress resolved any doubt on that score by including in Section 5 of the TCA, titled "Severability," a broad severability clause that expressly provides that "[i]f any provision of . . . the *regulations* promulgated under this division . . . is held to be invalid, the remainder of . . . *such regulations* . . . shall not be affected and shall continue to be enforced to the fullest extent possible." 21 U.S.C. § 387 (note) (emphasis added). That provision answers this question, but even if it did not, FDA devoted an entire section of the Rule to severability that explained in detail that "in a circumstance where some but not all of the rule's provisions are invalidated, FDA's intent is for the other provisions to go into effect." 85 Fed. Reg. at 15,695; *see also id.* (providing non-exhaustive list of specific examples in which severability may be relevant and what FDA's intent is with respect to severability in each example).

In its prior ruling, the Court held that it could not sever the Rule's graphic warnings from the textual warnings because the TCA provides that color graphics should "accompany" the textual warnings. *See R.J. Reynolds*, 2022 WL 17489170, at *18 (citing 15 U.S.C. § 1333(d)[1]). As the Court correctly observed, it is a "fundamental rule of statutory interpretation" that "specific provisions trump general provisions." *Id.* (quoting *Navarro-Miranda v. Ashcroft*, 330 F.3d 672, 676 (5th Cir. 2003)). On the question of *severability*, however, it is the TCA's severability provision that is the more specific command as compared to the more general language about color graphics.

As to the second prong, FDA explicitly found that severance would render the Rule workable: *See* 85 Fed. Reg. at 15,695 ("FDA has considered each provision independently and concluded that the individual portions of this rule are workable on their own."). That conclusion is entitled to deference. Although the Rule as a whole will best promote greater understanding of the health risks

of smoking, even portions of the Rule would be an improvement over the stale Surgeon General's warnings. FDA determined that *each* warning "demonstrate[s] statistically significant improvements, as compared to the current Surgeon General's warnings" with respect to FDA's key "new information" and "self-reported learning" metrics (as well as many other of FDA's metrics). *Id.* at 15,658. Moreover, as the Fifth Circuit implied, *see R.J. Reynolds*, 96 F.4th at 873, the severability analysis requires consideration of each image-warning pair separately. Because any one warning statement does not depend on the others for its meaning or effectiveness, vacating a portion of the Rule would still leave a "sensibl[e]" regulation in place. *MD/DC/DE Broadcasters*, 236 F.3d at 22.

B. Nationwide relief is inappropriate.

Though Plaintiffs request a universal "postponement" of the effective date of the Rule, relief should extend at most to the parties before the Court. *See, e.g.*, *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979) (injunctive relief may "be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs"); *Cargill v. Garland*, 57 F.4th 447, 472 (5th Cir. 2023) (plaintiff's remedy "must be tailored to redress the plaintiff's particular injury" (quoting *Gill v. Whitford*, 585 U.S. 48, 73 (2018))), *aff'd*, 602 U.S. 406 (2024). In granting Plaintiffs' summary judgment motion, this Court held that Fifth Circuit precedent permits the universal remedy of vacatur. *See R.J. Reynolds*, 2022 WL 17489170, at *21. But for four reasons, such relief is not warranted here.

First, Plaintiffs have not yet moved for summary judgment—they have only sought universal relief under § 705, which authorizes courts to "postpone the effective date of an agency action or . . . preserve status or rights pending" judicial review. 5 U.S.C. § 705. But there is nothing to postpone—as noted, the Rule has been in effect for months, and Plaintiffs cannot seek to "postpone" it now. At most the Court could "preserve status or rights pending" judicial review. That statutory language, coupled with the ordinary Article III principles cited above, counsels for Plaintiff-specific relief.

Second, even if universal remedies are permissible under the APA, nothing in the APA or Fifth Circuit precedent *mandates* a universal remedy in all cases. The APA was enacted against a background principle that statutory remedies should be construed in accordance with "traditions of equity practice." *Hecht Co. v. Bowles*, 321 U.S. 321, 329 (1944). Accordingly, the Court has discretion

to enter tailored, party-specific relief. *Cf. Cargill*, 57 F.4th at 472 (recognizing courts have authority to grant "more limited remedy" than universal vacatur).

Third, nationwide relief would be particularly unwarranted here given that another district court is currently considering a similar challenge to the Rule. *See Philip Morris USA, Inc. v. FDA*, No. 2:24-cv-00143 (S.D. Ga.). Universal relief could render any order by the Southern District of Georgia meaningless, as a practical matter. It would also preclude appellate courts from testing claims substantially similar to Plaintiffs' in other jurisdictions. *See L.A. Haven Hospice, Inc. v. Sebelius*, 638 F.3d 644, 664 (9th Cir. 2011) (nationwide relief may be "inappropriate" where it prevents "important or difficult questions of law" from being addressed "in multiple decisions by the various courts of appeals").

Fourth—and most significantly—the text of the TCA makes clear that Congress did not intend courts to grant universal remedies under this statute. Although the Court did not discuss this issue in its prior opinion, in the TCA's severability clause, Congress specified that, even if "the application of any [] provision [of the TCA] to *any person* or circumstance is held to be invalid, the remainder of [the TCA] . . . or the application of such provision to *any other person* or circumstance shall not be affected and shall continue to be enforced to the fullest extent possible." 21 U.S.C. § 387 (note) (emphases added). Thus, regardless of what the APA does or does not permit as a general matter, *see R.J. Reynolds*, 2022 WL 17489170, at *18-21 (discussing remedies under the APA), the Court should follow the more specific, and more recent, statutory language in the TCA, which expressly precludes universal relief that would run to non-parties.

CONCLUSION

For these reasons, the Court should deny Plaintiffs' motion to postpone the Rule's effective date and enter summary judgment for Defendants on all remaining claims.

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